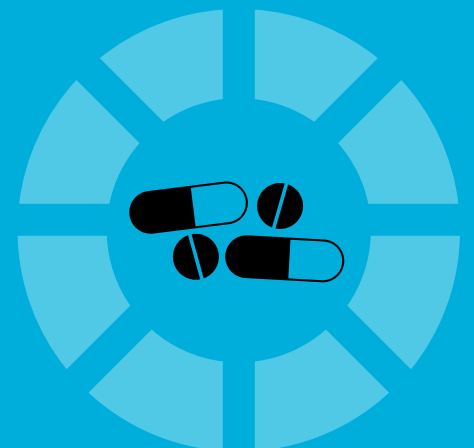


GERMANY

PHARMACEUTICALS & HEALTHCARE REPORT

INCLUDES 10-YEAR FORECASTS TO 2019





Germany Pharmaceuticals & Healthcare Report Q1 2010

Including 5-year and 10-year industry forecasts by BMI

Part of **BMI's** Industry Survey & Forecasts Series

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Executive Summary

In **BMI**'s Business Environment Ratings (BER) for Q110, Germany rose to pole position, among the nine Western European markets surveyed, having previously been ranked second behind Switzerland. The ratings criteria serve to reinforce our estimation of the country's potential owing to its strong emphasis on the regulatory environment, despite a major focus on cost-containment and industry-wide dissatisfaction over pricing and reimbursement practices. **BMI** calculated that Germany's pharmaceutical expenditure was EUR37.4bn (US\$55.0bn) in 2008, with the sales of medicines at consumer prices forecast to rise by a compound annual growth rate (CAGR) of only 2.18% in local currency terms to 2014. In 2009 the market value is expected to increase marginally, to reach EUR38.2bn (US\$53.7bn), driven by demand rather than pricing considerations. In fact, continued downward pressure on prices can be expected according to the country's industry associations.

Nevertheless, according to a study published in September 2009 by the Institute of Pharmacology at the University of Heidelberg in Germany, patients in Germany pay significantly more for their medicines than those in other European countries. The study attributes the high cost of medicines to the lack of effective price controls, claiming that the mechanisms for authorities and statutory insurance companies to reduce drug prices do not apply when a novel drug is brought into the market. Previous studies have highlighted the imposition of value-added tax (VAT) on pharmaceuticals – in comparison to the VAT-exempt status of medicines in most other European countries – and prescription volumes as key drivers of increased pharmaceutical spending in the country.

In the light of a difficult economic situation – after a disastrous 2009, we forecast economic expansion of just 0.9% in 2010 – German authorities have continued to implement a variety of cost-containment measures. In September 2009, Germany's healthcare cost-effectiveness regulator IQWiG recommended that health insurers in the country stop reimbursing memantine, an Alzheimer's disease drug, claiming that the drug fails to provide any benefit to patients or caregivers. Since the start of the year, after recommendations by the Federal Joint Committee (G-BA), second opinions by physicians for reimbursable prescriptions of high-cost treatments for pulmonary arterial hypertension (PAH) have been mandatory. **BMI** believes that, despite only initially being applicable to a small patient group, introducing second opinions to prescriptions will introduce an unnecessary level of bureaucracy to the system, therefore slowing patients' access to essential medicines.

Despite the challenges, the German pharmaceutical marketplace remains a dynamic one. For example, in August 2009, local biopharmaceutical company **Apogenix** received EUR2.6mn (US\$3.6mn) from the federal government to help the company to develop chronic inflammatory disease and oncology candidates. The grant is part of a EUR40mn (US\$56.3mn) scheme for businesses in Germany's Rhine-Neckar biotech cluster. In the same month, Belgian pharmaceutical group **UCB** and Swiss drugmaker **Novartis** signed a licensing deal for cardiovascular and diabetes products in order to expand in Germany.

SWOT Analysis

Germany Pharmaceuticals And Healthcare Industry SWOT

- Strengths**
- One of the largest pharmaceutical markets in Western in Europe
 - Several major drug multinationals including Bayer-Schering, Boehringer Ingelheim and Merck KGaA are based in Germany
 - Germany's regulatory environment, based on EU directives, is one of the most transparent and among the fairest in the world
 - A strong euro, declining R&D investment and unfavourable regulatory conditions have contributed to rising exports in recent years
 - VAT imposed on pharmaceuticals has contributed to value growth
 - Germany boasts a strong generics segment
- Weaknesses**
- Market growth has been sluggish in recent years, largely owing to increasingly harsh government cost-cutting measures, including de-reimbursement, a fixed-level drug price support scheme and reference pricing
 - Some companies choosing not to launch innovative medicines in Germany
 - Following the de-reimbursement of certain OTC products at the beginning of 2004, the sector has stagnated, though free-pricing has helped
 - Restrictive pharmacy ownership legislation preventing development of chains
- Opportunities**
- Generics market is growing robustly at present, with the government's cost-containment-focused policy and a significant number of patent expiries driving growth
 - Demographic and epidemiological profiles provide expansion opportunities for manufacturers of chronic treatments
 - The prescription market in Germany, already very strong, should increase its share of total as the OTC segment growth slows due to adverse economic trends
 - Germany's drug import market has grown notably in recent years and is likely to expand further
- Threats**
- The new coalition government is preparing measures to reduce pharmaceutical costs further, although this may deter multinational investment and slow short-term market growth
 - Relations between the government and industry have deteriorated notably, which will negatively impact state investment in and support of the segment
 - The branded drugs market is likely to be adversely affected by the government's pharmacy discount schemes, and a large number of patent expiries in the short to middle term
 - Investment in the drugs sector will continue to be hampered by the difficult operating environment
 - Political discord over health insurance market changes to preclude better planning in regards to pharmaceutical expenditure
 - Imports will remain disadvantaged by restrictive reimbursement policies

Germany Political SWOT

- | | |
|----------------------|--|
| Strengths | <ul style="list-style-type: none">▪ A strong consensual and stable democracy which has been consolidated over the last six decades. Germany's is a key voice at the heart of the European Union |
| Weaknesses | <ul style="list-style-type: none">▪ The emphasis on consensus and consultation means the political system can be slow-moving and unable to change rapidly. High unemployment, particularly in Eastern Germany where democratic traditions are less strongly rooted, has led to growth of far left and far right parties, outside of the political mainstream |
| Opportunities | <ul style="list-style-type: none">▪ There is an opportunity to re-define the German social contract in a way that allows the country to compete more effectively on global markets. The emergence of a centre-right coalition, with a strong Free Democrat element, after the next elections could be a trigger for key changes |
| Threats | <ul style="list-style-type: none">▪ The continued fragmentation of parliament between five political parties - together with the long-term decline in the popularity of the main two parties - is already making Germany harder to govern. There is a risk that this situation could yet get worse after the 2009 elections |

Germany Economic SWOT

- | | |
|----------------------|---|
| Strengths | <ul style="list-style-type: none">▪ The largest economy in Europe, with high R&D spend and an almost unrivalled reputation for world-class quality in manufactured goods. Although competing for power and operating from ideologically different perspectives, both main parties now share the view that some degree of market-friendly reforms are necessary to boost economic recovery |
| Weaknesses | <ul style="list-style-type: none">▪ High costs across the manufacturing base, coupled with a relatively high value currency, the euro. A large and costly public sector and welfare system: while part and parcel of the German consensual industrial relations model, also a heavy drag on company costs and agility |
| Opportunities | <ul style="list-style-type: none">▪ Expansion into the "new Europe" and other areas by German multinationals, so as to combine German standards of manufacturing quality with the more competitive labour costs of the host areas. Any increase in global economic activity, which carries with it increased demand for high-end manufactured products – Germany's particular area of expertise |
| Threats | <ul style="list-style-type: none">▪ The poor global economic climate poses a greater threat to Germany than to many other developed states. Not only is Germany the world's largest exporter, but it specialises in high-end manufactured goods and capital products, which have been particularly badly hit by the slow-down in both G7 and emerging markets |